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APPLICATION NUMBER:

203284Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
Application Number(s) 203284
Priority or Standard S

Submit Date(s) 12-23-11
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Division / Office DGIEP

Reviewer Name(s) Nancy F. Snow
Review Completion Date 11-27-12

Established Name Glycerol Phenylbutyrate
(Proposed) Trade Name Ravicti

Therapeutic Class Not established
Applicant Hyperion Therapeutics

Formulation(s) Liquid
Dosing Regimen TID with meals
Indication(s) Adjunctive therapy for chronic
management of patients with
Urea Cycle Disorders
Intended Population(s) Pediatric and adult patients

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